

ARAZIL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARAZIL?

ARAZIL contains the active ingredient donepezil hydrochloride. ARAZIL is used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type.

For more information, see Section [1. Why am I using ARAZIL?](#) in the full CMI.

2. What should I know before I use ARAZIL?

Do not use if you have ever had an allergic reaction to donepezil hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARAZIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARAZIL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARAZIL?

- The usual starting dose for ARAZIL is one 5 mg tablet each day.
- After one month, your doctor will assess your response and may increase your dose to one ARAZIL 10 mg tablet a day.

More instructions can be found in Section [4. How do I use ARAZIL?](#) in the full CMI.

5. What should I know while using ARAZIL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARAZIL.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the

	dosage without checking with your doctor first.
Driving or using machines	<ul style="list-style-type: none"> ● ARAZIL may cause fatigue, dizziness and muscle cramps, especially at the start of treatment. ● Be careful driving or operating machinery until you know how ARAZIL affects you. ● Alzheimer’s disease may affect your ability to drive or operate machinery. ● Ask your doctor whether it is safe for you to continue to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep your tablets in their blister pack until it is time to take them. ● Keep your tablets in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ARAZIL?](#) in the full CMI.

6. Are there any side effects?

Common side effects include heartburn, indigestion, stomach pain, headache, dizziness, difficulty in sleeping, unusual tiredness, feeling sick, diarrhoea, vomiting, loss of appetite, weight loss, bruising, muscle cramps, joint pain, tingling or numbness of the hands or feet, depression, unusual dreams, agitation, aggressive behaviour, difficulty in urinating or passing urine more often.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARAZIL®

Active ingredient: *donepezil hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARAZIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARAZIL.**

Where to find information in this leaflet:

- [1. Why am I using ARAZIL?](#)
- [2. What should I know before I use ARAZIL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARAZIL?](#)
- [5. What should I know while using ARAZIL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARAZIL?

ARAZIL contains the active ingredient donepezil hydrochloride. ARAZIL is an acetylcholinesterase inhibitor. They are thought to work by increasing the level of a chemical called acetylcholine in the brain.

ARAZIL is used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type. ARAZIL will not cure the disease, but should help your memory and improve your thinking capacity.

2. What should I know before I use ARAZIL?

Warnings

Do not use ARAZIL if:

- you are allergic to donepezil hydrochloride, piperidine derivatives or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- the expiry date on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- plan to go to hospital for surgery that requires a general anaesthetic.
- have any other medical conditions, including
 - heart problems (such as irregular or very slow heartbeat, heart failure, myocardial infarction)

- a heart condition called ‘prolonged QT interval’ or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have ‘prolonged QT interval’
- low levels of magnesium or potassium in your blood
- stomach problems, particularly gastric or duodenal ulcer
- seizures or fits (epilepsy)
- asthma or obstructive lung disease
- loss of memory or other mental capacity due to stroke or blood vessel problems
- tendencies toward aggressive behaviour.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Children

ARAZIL is not recommended for use in children.

The safety and effectiveness of ARAZIL in children has not

been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ARAZIL and affect how it works.

Tell your doctor or pharmacist if you are taking any medicines for any other condition, including

- any other medicine for dementia
- medicines used to relieve stomach cramps or spasms, Parkinson's disease or travel sickness
- medicines used to relax muscles
- medicines used in general anaesthesia
- anti-fungal medicines e.g. ketoconazole
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- dexamethasone, a corticosteroid medicine
- medicines for heart rhythm problems e.g. amiodarone, sotalol
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines used to treat irregular heartbeat e.g. quinidine
- medicines used to treat

- difficulty in passing urine
- arthritis, pain or inflammation known as non-steroidal anti-inflammatory drugs (NSAIDs)
- high blood pressure or fast heartbeat
- asthma
- diarrhoea
- epilepsy - carbamazepine, phenobarbital or phenytoin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARAZIL.

4. How do I use ARAZIL?

How much to take

- The usual starting dose for ARAZIL is one 5 mg tablet each day.
- After one month, your doctor will assess your response and may increase your dose to one ARAZIL 10 mg tablet each day.
- Depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

Follow the instructions provided with the medicine.

Do not exceed the recommended dosage.

When to take ARAZIL

Take your medicine every night just before you go to bed.

Taking it at the same time each day will have the best effect.

It will also help you remember when to take it.

How to take ARAZIL

Swallow the tablets whole with a full glass of water.

Do not divide the tablet into halves.

ARAZIL can be taken with or without food.

Continue taking your medicine for as long as your doctor

tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

It may take several weeks for your medicine to take effect, so do not be discouraged if you do not see an improvement straight away.

If you forget to use ARAZIL

If you forget to take a tablet, just take one tablet the following day at the usual time then continue as normal.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you forget to take your medicine for more than one week, call your doctor before taking any more.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much ARAZIL

If you think that you have used too much ARAZIL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ARAZIL?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using ARAZIL.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

Do not take this medicine to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARAZIL affects you.

This medicine may cause fatigue, dizziness and muscle cramps especially at the start of treatment or if the dose is increased. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In addition, Alzheimer's disease may affect your ability to drive or operate machinery.

Ask your doctor whether it is safe for you to continue to drive or operate machinery.

Looking after your medicine

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine, if you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">● heartburn, indigestion, or stomach pain● headache or dizziness● difficulty in sleeping● unusual tiredness● feeling sick, diarrhoea, vomiting	Speak to your doctor or pharmacist if you have any of these side effects and they worry you.

Common side effects	What to do
<ul style="list-style-type: none"> ● loss of appetite, weight loss ● bruising ● muscle cramps, joint pain ● tingling or numbness of the hands or feet ● depression, unusual dreams ● agitation, aggressive behaviour ● difficulty in urinating or passing urine more often ● changes in sexual drive, particularly increase 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● seeing, feeling or hearing things that are not there ● trembling and shaking of the hands and fingers, shuffling walk and stiffness of the arms and legs 	<p>Tell your doctor as soon as possible if you notice any of these serious side effects which may require medical attention.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● bending of the back forward and to one side (Pisa syndrome) ● severe upper stomach pain, often with nausea, vomiting and fever ● changes in the heart activity which can be seen on an electrocardiogram (ECG) called 'prolonged QT interval' ● fast irregular heartbeat, fainting which could be the symptoms of a life-threatening condition known as Torsade de Pointes 	

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> ● any breathing difficulties ● sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very serious side effects	What to do
<p>wheezing or difficulty breathing</p> <ul style="list-style-type: none"> ● fainting, especially if you have a slow or irregular heartbeat ● vomiting blood or material that looks like coffee grounds ● black sticky bowel motions (stools) ● convulsions or fits ● weakness, shortness of breath, yellowing of the skin, dark brown urine and stomach pain ● sudden increase in body temperature, sweating, muscle stiffness, or altered consciousness (awareness of oneself and ones surrounding) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARAZIL contains

Active ingredient (main ingredient)	donepezil hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● lactose monohydrate● maize starch● hypromellose● microcrystalline cellulose● magnesium stearate● Opadry Complete film coating system White

	Y-1-7000 (ID 1475) or Instacoat Universal White A05G15138 (ID 144681) containing Hypromellose, Macrogol/PEG MW 400, and Titanium dioxide
Potential allergens	sugars as lactose and trace quantities of sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What ARAZIL looks like

ARAZIL 5 mg tablet is 7 mm white, film coated, round tablets embossed with "DL" over "5" on one side and "G" on the reverse (AUST R 167692).

ARAZIL 10 mg tablet is 9 mm white, film coated, round tablets embossed with "DL" over "10" on one side and "G" on the reverse (AUST R 167693).

Who distributes ARAZIL

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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ARAZIL® is a Viatris company trade mark

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